

Remarks/Arguments

In the most recent Office Action in this case, which Action was dated December 8, 2003, the Examiner objected to the specification with respect to what appears to be a typographical error on page 2 in the specification, rejected claims 1 and 2 technically under 35 U.S.C. § 101 as being directed to non-statutory subject matter, and subsequently rejected claims 1-4, inclusive, under 35 U.S.C. § 103 on the basis of a proposed combination of U.S. Patent No. 6,507,753 to Xue et al., and with an article authored by Wagner et al., entitled "Evaluation of a QRS scoring system for estimating myocardial infarct size."

Applicants have carefully reviewed the Examiner's Action and comments, along with the specification, claims and drawings in this case, and the contents of the two cited and applied prior art references, and by the present Amendment, propose certain changes and advance certain arguments and remarks which are believed (a) to respond to the Examiner's technical objections, and (b) to point out how and why applicants' claims, as now presented in this case on the basis of entry of this Amendment, are clearly distinguishable over the art of record, and are therefore patentable.

To begin with, the Examiner has correctly noted a typographical error on page 2 in the specification, and that error is repaired by the present Amendment. Additionally, applicants (a) have cancelled claims 3 and 4 without prejudice, (b) have currently amended claims 1 and 2 to address the Examiner's rejection under 35 U.S.C. § 101, and to provide additional emphasis on the very unique confounder-history capability feature of the present invention, and (c) have introduced minor text changes on pages 2 and 3 in the specification to provide, on page 2, fuller definitions of

certain terms which are employed in the specification, claims and drawings, as filed, in this case, and on page 3, correction for another discovered typographical error.

As applicants' claims now clearly point out with even greater than original emphasis, the method of this invention is one which deals in a unique way with performing detection and characterization of what is known in the art as an *old*, or *chronic*, myocardial infarct. Very specifically the method of the invention is one which provides for such detecting and characterizing *specifically in the presence of a history of confounding conditions associated with a particular subject*.

It is very important for the Examiner to note that applicants' claimed invention is directed to *old* or *chronic* myocardial infarct situations, as distinguished from *acute* myocardial infarct situations.

The combination of references proposed by the Examiner is simply inapplicable to this world of *old*, or *chronic* myocardial infarcts. The Xue et al. reference is squarely focused upon *acute* myocardial infarcts -- a region of work wherein the ratios set forth in applicants' specification, claims and drawings have absolutely no bearing.

Categorically contrary to what the Examiner suggests in his Action, no one skilled in the art "would have recognized that Xue et al. did not intend to limit their invention to ST-segment and T-wave criteria only...." Indeed, one skilled in the art would immediately recognize that the Xue et al disclosure which deals with *acute* MI, has no relevance to any use of the R/Q and R/S ratios which applicants herein teach in the truly relevant sphere of *old*, or *chronic*, MI. To suggest anything that would propose modifying Xue et al. by bringing into play some form of

recognition of the ratios with respect to which applicants invention is concerned is to suggest, in a certain manner of thinking, effective nullification of the Xue et al. utility. Thus, the importation into a Xue et al. setting of ratio subject matter as discussed in the Wagner et al. publication involves an inappropriate blending of medical “apples and oranges”..

Not only is the prior art devoid of any teaching or suggestion which would lead to a combination like that proposed by the Examiner, further setting applicants’ invention apart from anything known in the art is that it proposes a method wherein the detecting and characterizing described by it takes place in a setting involving the presence, in a subject, of a history of the clearly described confounding conditions – conditions which include the mentioned so-called conduction abnormalities and ventricular hypertrophies, illustrations of which are given in the specification, and which are demonstrated in the data presented in the Data Tables provided in this case.

For these reasons, applicants respectfully submit that the cited and applied art of record simply cannot be combined in any rational way to suggest applicants’ invention, not only because of the fact (a) that Xue et al., with respect to which the Examiner suggests the importation of certain ratio considerations, would become effectively inoperative in a setting focusing on those ratios which have no applicability to the Xue et al. world of *acute* myocardial infarcts, but also because of the fact (b) that there is simply no reference known which describes methodology for performing the steps of the present invention in a setting where a particular subject has a history of the mentioned confounding conditions.

Accordingly, favorable reconsideration of this application, and allowance of the

two claims remaining in this case on the basis of entry of the present Amendment, are respectfully solicited.

As a final commentary herein, filed in the U.S. Patent and Trademark Office, along with the present Amendment, is an Information Disclosure Statement listing, and accompanied by copies of, six articles in the prior art which applicants believe should be read and reviewed by the Examiner as providing illustrations of the background of the present invention, which articles should indeed help to illustrate, in the file history of this case, prior art material which clearly demonstrates the lack in the prior art of any recognition that the kind of detecting and characterizing of old myocardial infarcts, as proposed by the present invention, can be performed in a setting where confounding conditions exist. While it is apparent, particularly in the case of the articles wherein Dr. Selvester, who is one of the named inventors hereof, is a co-author, that these articles should have been submitted when the application was filed, they were not provided to the attorney who filed the application. These articles were brought to the attention of the attorney of record during discussion with employees of assignee during meetings to prepare this response, and are now submitted for consideration by the U. S. Patent and Trademark Office. A PTO Form 2038 credit card authorization in the amount of \$180.00 IAW 37 C.F.R. § 1.97(d) and 37 C.F.R. § 1.17(p) is submitted herewith.

In light of the foregoing amendment and remarks, the Examiner is respectfully requested to reconsider the rejections and objections state in the Office action, and pass the application to allowance. If the Examiner has any questions regarding the amendment or remarks, the Examiner is invited to contact Attorney-of-Record Jon M. Dickinson, Esq., at 503-504-2271.

Request for Extension of time in Which to Respond

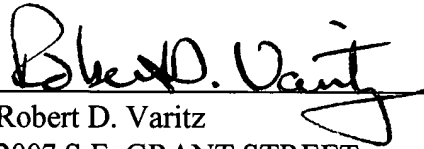
Applicants hereby request an extension of time under 37 C.F.R. § 1.136 to respond within the second month following the end of the shortened statutory period. A PTO Form 2038 credit card authorization in the amount of \$210.00 accompanies this Request. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any over-payment to Account No. 22-0258.

Customer Number

23855

Respectfully Submitted,

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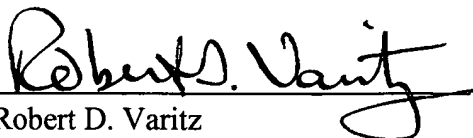
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I hereby certify that the attached Response to Office Action under 37 C.F.R. § 1.111, Supplemental IDS with references, and Two (2) PTO Form 2038 credit card authorization in the amount of \$210.00 + \$180.00 are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to:

Mail Stop Fee Response
Commissioner for Patents
P.O. Box 1450
Washington, D.C. 22313-1450



Robert D. Varitz